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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,865

02/07/2005

Hideko Kosaka

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EXAMINER

GERIDO, DWAN A

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,865	Applicant(s) KOSAKA, HIDEKO	
	Examiner Dwan A. Gerido, Ph.D.	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-8,12,13 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-8,12,13 and 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 5, 6, 8, 12, 13, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Proffitt et al., (US 2005/0106748) in view of Sujeth (US 5,772,696).

4. With regards to claims 1, 5-8, 12, 13, and 17-19, Proffitt et al., teach a method of using a protein assay indicator for determining albumin in a urine sample. Specifically, Proffitt et al., teach bromine, and hydrogen constituents bound to the indicator in the exact positions described by the instant claims (paragraph 0040, structure B). Additionally, Proffitt et al., teach utilizing dyes identical to those of the instant application, namely eosin B, eosin Y, rose bengal, and phloxine B (paragraph 0038), which would exhibit identical properties as stated in the instant claims. Proffitt et al., also teach albumin as the protein to be measured (paragraphs 0092, 0097). Proffitt et al., do not explicitly teach chlorine as a substituent for the test indicator. However,

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Proffitt et al., do recite utilizing halogenated alkyl substituent groups to increase solubility of an organic compound in aqueous solutions (paragraph 0036). This feature of the instant claims is being read as a substitution of a known element. The MPEP states that when substituting one element for another known in the field, the combination must do more than yield a predictable result. Both bromine and chlorine are halogens, thus the elements would be expected to exhibit similar results when bound to the indicator of the instant claims. Therefore, it would have been obvious to utilize any halogen such as chlorine as substitution requires only routine skill in the art. Proffitt et al., do not teach the indicator with sodium bound to the hydroxyl and carboxyl groups.

Sujeeth teaches a process for purification of water soluble dyes utilizing an organic molecule of identical structure (eosin Y) as that of the instant claims wherein sodium is bound to the hydroxyl and carboxyl groups (column 5 lines 30-45). Sujeeth teaches that it is advantageous to utilize sodium bound to the hydrogen and carboxyl groups as a means of increasing solubility of the indicator. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Proffitt et al., in view of Sujeeth to utilize sodium bound to an indicator in order to increase water solubility of the indicator as taught by Sujeeth.

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Proffitt et al., (US 2005/0106748) in view of Sujeeth (US 5,772,696) as applied to claim 1 above, and further in view of Lau (EP 0,361,244).

6. With regards to claim 7, Proffitt et al., in view of Sujeeth do not teach measuring an albumin concentration between 10 and 20 mg/dL.

Lau teaches a method of assaying urinary albumin wherein the normal concentration of urinary albumin is between 10 and 20mg/dL. Additionally, Lau teaches that normal urine protein concentration ranges from 2-8mg/dL (page 2 lines 40-42). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Proffitt et al., in view of Sujeeth, in further view of Lau in order to determine renal abnormalities due to increased or urinary protein levels as taught by Lau.

7. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over over Proffitt et al., (US 2005/0106748) in view of Sujeeth (US 5,772,696) as applied to claim 13 above, and further in view of Bullard et al., (US 3,963,442).

8. With regards to claim 18, Proffitt et al., do not teach a sensitizer for coloration sensitivity within the test piece.

Bullard et al., teach a colorimetric indicator wherein colorimetric indicators sensitive to pH are placed in the test sheet (column 8 lines 47-49, table II). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Proffitt et al., in view of Sujeeth with the sensitizer of Bullard et al., in order to provide colorimetric means of verifying pH of the solution.

9. With regards to claim 19, Bullard et al., teach polyethylene glycol as a colorimetric sensitizer. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Proffitt et al., in view of Sujeeth with the polyethylene glycol sensitizer of Bullard et al., in order to provide a water soluble sensitizer.

Response to Arguments

10. Applicant's arguments with respect to claims 1, 5-8, 12, 13, and 17-19 have been considered but are moot in view of the new ground(s) of rejection.

11. Applicant's have argued that the combination of Proffitt et al., in view of Sujeeth do not teach the invention as claimed. The examiner respectfully disagrees. Reference to Proffitt et al., teach an indicator identical to the base compound of the instant claims for assaying albumin proteins in a urine sample. Proffitt et al., also teach the indicator having halogenated alkyl groups and specifically bromine as substituents. As detailed above, Proffitt et al., do not teach chlorine as a substituent; however, this limitation is being read as substitution of a known element which would have been obvious to one of ordinary skill in the art.

Reference to Sujeeth is relied upon solely for the teaching of adding sodium to an assay indicator as a means of increasing water solubility of the indicator. It is the examiners position that one of ordinary skill in the art would have found it obvious to modify Proffitt et al., with the teachings of Sujeeth in order to increase water solubility of the indicator, and that the modification of Proffitt et al., in view of Sujeeth does not involve impermissible hindsight as argued by applicants.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwan A. Gerido, Ph.D. whose telephone number is (571)270-3714. The examiner can normally be reached on Monday - Friday, 9:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/
Primary Examiner, Art Unit 1797

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